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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/333,680	11/03/94	WANG	Q CELL16

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HM31/0831

EXAMINER

PRIEBE, S

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 08/31/98

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
08/333,680

Applicant(s)  
Wang et al.

Examiner  
Scott D. Priebe, Ph.D.

Group Art Unit  
1632



☒ Responsive to communication(s) filed on Jul 22, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 37-50, 52, 54, 56, and 57 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☒ Claim(s) 39-45, 48-50, and 57 is/are allowed.

☒ Claim(s) 37, 38, 46, 47, 52, 54, and 56 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

The amendment filed 7/22/98 has been entered. Claims 37-39 and 46-50 have been entered. Claims 37-50, 52, 54, 56 and 57 are pending.

#### ***Specification***

The abstract of the disclosure is objected to because it is not commensurate in scope with the claimed invention. Correction is required. See MPEP § 608.01(b). The claims are drawn to adenoviral vectors lacking E1, E2A and/E4 and packaging cells expressing E1, E2A and/or E4. The abstract is limited to E1 and E4, failing to mention E2A.

#### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 37, 38, 46, 47, 52, 54, and 56 remain rejected under 35 U.S.C. 102(e) as being anticipated by Gregory et al., US 5,670,488 for the reasons of record set forth in the Office action of June 22, 1998 repeated below.

Gregory et al. discloses PAV vectors and adenovirus which in which the only adenoviral sequences present are the ITRs and packaging sequence and a transgene in place of the deleted E1, E2A, E3 and E4 regions (including E4 ORFs 3 & 6) *inter alia*. See Gregory et al. Fig. 16A & 16B; col. 12. lines 7-50; col. 43, line 5 to col. 44, line 34.

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Applicant's arguments filed July 22, 1998 have been fully considered but they are not persuasive. It is argued that the adenoviral vectors and virions disclosed in Gregory et al. do not meet all the limitations of the claims nor are the PAV vectors and virions enabled by the disclosure in Gregory et al.

On the first point, it is unclear what limitations in the instant claims are lacking in the PAV vectors of Gregory et al. All adenoviral coding regions are deleted and require complementation by a helper virus in order to be packaged into adenoviral capsids. The claims use open language and do not preclude the deletion of adenoviral coding sequences other than the early regions recited. The claims do not recite that the resulting adenoviral vector or adenovirus can be complemented by a packaging cell line that expresses only adenoviral E1, E2A and or E4 coding sequences. The flaw in applicants' argument is that the claims recite only what adenoviral sequences are missing, not what adenoviral sequences that are present. It is argued that Gregory et al. does not teach how to provide the necessary adenoviral proteins *in trans* to complement deletion of the adenoviral sequences of the PAV. This assessment is in error, attention is respectfully directed to col. 43, lines 41-57 where the reference teaches cotransfecting the PAV vector with a helper adenoviral genome, preferably packaging defective, which supplies the essential adenoviral products. No evidence has been provided that this method of producing viral particles is inoperative. It is true that Gregory et al. does not enable generating virus particles by transfecting a packaging cell line which expresses only the missing adenoviral products, i.e. E1,

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E4 and optionally E2A, but the claims are not limited to adenovirus that can be propagated on such cells.

*Allowable Subject Matter*

Claims 39-45, 48-50 and 57 are allowed.

*Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX number is (703) 308-4242 or 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and

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1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 9 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasmine Chambers, Ph.D., can be reached on (703) 308-2035.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*SDP*

Scott D. Priebe, Ph.D.  
Patent Examiner  
Art Unit 1632

August 14, 1998

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